**In the Title:**

Please amend the Title to read:

- - Methods of Making a Multilumen Catheter Assembly - -

**In the Specification:**

Please amend various paragraphs to read as follows:

**[0016]** In another aspect of the present invention, the multilumen catheter assembly includes a unitary catheter having [[an]] a rounded exterior surface, a first lumen and a second lumen extending longitudinally therethrough, a distal end and a proximal end; and a first distal end tube defining a first longitudinally extending passageway and a second distal end tube defining a second longitudinally extending passageway, where the first and the second distal end tubes extend distally from the distal end of the unitary catheter, the first passageway in the first distal end tube being in fluid communication with the first lumen, the second passageway in the second distal end tube being in fluid communication with the second lumen and the first and second distal end tubes are capable of independent movement with respect to each other.

**[0026]** Figure [[2e]] 2f is an enlarged cross-sectional view of an alternative embodiment of the multilumen catheter assembly of Figure 1 taken along line 1a-1a.

**[0070]** The adhesive, or splittable membrane, performs multiple functions. First, the membrane joins the tubes 14, 16 so that the tubes 14, 16 can be easily manipulated, particularly where the membrane is unbroken. Where the membrane is completely intact, the catheter assembly 6 can be manipulated as a single catheter (e.g., the unitary catheter 12). Second, the membrane allows the first and the second distal end tubes 14, 16 to be at least partially longitudinally split apart from each other, without damaging the outer walls 44 of the tubes 14, 16, to allow independent movement of the split portions in the vessel or other area to be catheterized. The membrane is constructed to split easily when the first and the second tubes 14,

16 are separated from each other, thereby tearing or splitting before the opposing forces exerted on the tubes 14, 16 reach a level sufficient to cause damage thereto. However, the membrane should be sufficiently strong to resist tearing during normal handling of the catheter assembly [[5]] 6.

**[0077]** The outer walls 44 of the first and the second distal end tubes 14, 16 can be separate (unattached) and independent over the Arrow "B" portion of the longitudinal length of the catheter assembly 8 of Figure 6 [[6)]], or the first and the second distal end tubes 14, 16 can be releasably attached (splittable) over this length. In either case, the cross section of the first and the second distal end tubes 14, 16, as shown in Figure 6b, illustrates that the outer walls 44 of the first and the second distal end tubes 14, 16, as well as the outer walls 39 of the first and second lumens 24, 26, are rounded or circular.

**[0081]** As known in the art, ~~hubs~~ hub 18 may be sealed, such as by bonding, adhering, heat molding, or through other attachment, to a distal end of an extension tube (or extender) and a proximal end of a tube or lumen. In one aspect of the invention, extension tubes are proximal portions of two separate lumens which are coated with an outer layer, perhaps by heat molding, to form a unitary body portion of the assembly. Accordingly, the extension tubes are continuous with the proximal ends of the lumens, and the hub 18 can be simply molded or otherwise adhered around the proximal ends of the lumens and around the distal ends of the extension tubes. In another aspect of the invention, the hub 18 (outer layer) is molded or otherwise adhered around some midpoint portion of a first and a second tube or lumen, creating extension tubes and a catheter assembly from one set of tubes or lumens. If either aspect, above, is the embodiment of the hub 18 incorporated into the catheter assembly 9 of Figure 7, it is understood that the proximal end 28, 30 of the first and second lumens 24, 26 occurs at the point where the extension tubes 20, 22 diagonally diverge from the hub 18.

**[0087]** Where releasable attachment using adhesive is employed in the present invention, the outer surfaces of the tubes are ~~reasonably~~ releasably joined using an adhesive having an adhesive strength, relative to the material forming the tubes, greater than the cohesive strength of

the adhesive. Since the adhesive is applied as a very thin layer or coating, it is not shown in the Figures. However, one of ordinary skill in the art would understand, based on this disclosure, that the adhesive is applied as a partial or complete coating on one or both of the outer walls 44 of the tubes 14, 16 such that when the tubes 14, 16 are pressed together, the outer walls 44 will adhere. As a result of using an adhesive which will adhere more strongly to the tubes ~~then~~ than to itself, the adhesive will initially hold the desired portion of the catheter assembly together, allowing manipulation of the catheter assembly in the same manner as a unitary, multi-lumen catheter. However, upon application of opposing transverse forces to distal end portions and/or the distal ends 32, 34, the adhesive will lose cohesive strength and separate longitudinally along the catheter assembly so that the tubes 14, 16 may be at least partially longitudinally split.

**[0089]** The catheter assemblies of the present invention can each have smooth, round distal ends 32, 34, which do not have protuberances, which can be points where clotting can begin. The distal ends 32, 34, which have smooth, round exterior surfaces that float freely within the vessel, do not provide a source of clot formation. The free-floating distal ends of the present invention provide beneficial aspects over an individual catheter tube, including no tendency to suction against an inside surface of the vessel wall, which minimizes the tendency of stenosis. The catheter assemblies of the present invention also have little tendency to kink, since the unitary catheter type configuration provides a good deal of support due to a thickness of its walls and cross section, and due to the smoothness of the separate distal end tubes.

**[0095]** The catheter assemblies of the present invention can be made of biocompatible plastics or elastomers, and preferably made of biocompatible elastomers. Suitable biocompatible plastics may be selected from materials such as polyurethane, polyethylene, homopolymers and copolymers of vinyl acetate such as ethylene vinyl acetate copolymer, polyvinylchlorides, homopolymers and copolymers of acrylates such as polymethylmethacrylate, polymethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate and hydroxymethyl methacrylate, polyurethanes, polyvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, polycarbonates, polyamides, fluoropolymers such as homopolymers and copolymers of polytetrafluoroethylene and polyvinyl fluoride, polystyrenes,

homopolymers and copolymers of styrene acrylonitrile, cellulose acetate, homopolymers and copolymers of acrylonitrile butadiene styrene, polymethylpentene, polysulfones, polyesters, polyimides, polyisobutylene, ~~polymethyistyrene~~ polymethylstyrene and other similar compounds known to those skilled in the art. It should be understood that these possible biocompatible polymers are included above for exemplary purposes and should not be construed as limiting.

**[0099]** If the catheter assemblies of the present invention are used for hemodialysis applications, the unitary catheter 12, the distal end tubes 14, 16, and the extension tubes 20, 22 are most preferably formed of a soft silicone elastomer having a hardness of from abut 75-A to about 85-A on a Shore durometer scale. Suitable, preferred elastomers include silicone or polyurethane elastomers, and most preferably polyurethane elastomers, such as, for example, Pelletane® polyurethane from Dow Corning, or Tecothane®, Carbothane® or Tecoflex® polyurethanes, available from Thermetics.

**[0101]** In one aspect of the present invention, the unitary catheter 12, the distal end tubes 14, 16, and the extension tubes 20, 22 are all formed of Carbothane® polyurethane of 85-A durometer. Alternatively, a preferred combination may be formed of a Tecoflex® polyurethane of durometer of about 80-A for the unitary catheter 12 and the distal end tubes 14, 16, and a Pelletane® polyurethane of durometer of about 80-A for the hub 18 and/or the extension tubes 20, 22. The additional components for attaching to dialysis or similar equipment, including luers, connectors and the like, are preferably formed of a polymeric and/or elastomeric material such as acetal, silicone 80-A or polyvinyl chloride. However, such connectors may be formed from any suitable material known or to be developed in the art for forming such connectors and/or adapters.

**[0115]** Another alternative to the methods described above for making the present invention includes arranging a first catheter tube and a second catheter tube in a substantially longitudinally parallel arrangement, preferably such that they are juxtaposed to each other [[,]] ; however, a gap may be present between the catheter tubes. Further, more than two catheter tubes may be used and similarly arranged. Each of the catheter tubes is preferably a single

lumen catheter [[,]]_; however, multilumen catheters may also be used for some applications. The first and the second catheter tubes each have a respective distal end, distal end portion, and at least one lumen in each catheter tube which extends longitudinally therethrough.